

PATENT COOPERATION TREATY

PCT

INTERNATIONAL PRELIMINARY REPORT ON PATENTABILITY

(Chapter II of the Patent Cooperation Treaty)

(PCT Article 36 and Rule 70)

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Applicant's or agent's file reference P814PC00	FOR FURTHER ACTION	
	See Form PCT/IPEA/416	
International application No. PCT/DK2004/000803	International filing date (day/month/year) 19.11.2004	Priority date (day/month/year) 21.11.2003
International Patent Classification (IPC) or national classification and IPC C07K14/205, C12N15/11, G01N33/569, C07K16/12, A61K39/02		
Applicant ACE BIOSCIENCES A/S et al.		

<ol style="list-style-type: none"> This report is the international preliminary examination report, established by this International Preliminary Examining Authority under Article 35 and transmitted to the applicant according to Article 36. This REPORT consists of a total of 10 sheets, including this cover sheet. This report is also accompanied by ANNEXES, comprising: <ol style="list-style-type: none"> <input checked="" type="checkbox"/> (<i>sent to the applicant and to the International Bureau</i>) a total of 8 sheets, as follows: <ul style="list-style-type: none"> <input checked="" type="checkbox"/> sheets of the description, claims and/or drawings which have been amended and are the basis of this report and/or sheets containing rectifications authorized by this Authority (see Rule 70.16 and Section 607 of the Administrative Instructions). <input type="checkbox"/> sheets which supersede earlier sheets, but which this Authority considers contain an amendment that goes beyond the disclosure in the international application as filed, as indicated in item 4 of Box No. I and the Supplemental Box. <input type="checkbox"/> (<i>sent to the International Bureau only</i>) a total of (indicate type and number of electronic carrier(s)) , containing a sequence listing and/or tables related thereto, in computer readable form only, as indicated in the Supplemental Box Relating to Sequence Listing (see Section 802 of the Administrative Instructions).
<ol style="list-style-type: none"> This report contains indications relating to the following items: <ul style="list-style-type: none"> <input checked="" type="checkbox"/> Box No. I Basis of the opinion <input type="checkbox"/> Box No. II Priority <input checked="" type="checkbox"/> Box No. III Non-establishment of opinion with regard to novelty, inventive step and industrial applicability <input checked="" type="checkbox"/> Box No. IV Lack of unity of invention <input checked="" type="checkbox"/> Box No. V Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement <input type="checkbox"/> Box No. VI Certain documents cited <input type="checkbox"/> Box No. VII Certain defects in the international application <input type="checkbox"/> Box No. VIII Certain observations on the international application

Date of submission of the demand 05.12.2005	Date of completion of this report 26.01.2006
Name and mailing address of the International preliminary examining authority:  European Patent Office - P.B. 5818 Patentlaan 2 NL-2280 HV Rijswijk - Pays Bas Tel. +31 70 340 - 2040 Tx: 31 651 epo nl Fax: +31 70 340 - 3016	Authorized Officer Groenendijk, M Telephone No. +31 70 340-3715 

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Box No. I Basis of the report

1. With regard to the **language**, this report is based on the international application in the language in which it was filed, unless otherwise indicated under this item.
 - This report is based on translations from the original language into the following language, which is the language of a translation furnished for the purposes of:
 - international search (under Rules 12.3 and 23.1(b))
 - publication of the international application (under Rule 12.4)
 - international preliminary examination (under Rules 55.2 and/or 55.3)
2. With regard to the **elements*** of the international application, this report is based on (*replacement sheets which have been furnished to the receiving Office in response to an invitation under Article 14 are referred to in this report as "originally filed" and are not annexed to this report*):

Description, Pages

1-66 as originally filed

Claims, Numbers

1-52 filed with the demand

Drawings, Sheets

1/20-20/20 as originally filed

a sequence listing and/or any related table(s) - see Supplemental Box Relating to Sequence Listing

3. The amendments have resulted in the cancellation of:
 - the description, pages
 - the claims, Nos.
 - the drawings, sheets/figs
 - the sequence listing (*specify*):
 - any table(s) related to sequence listing (*specify*):
4. This report has been established as if (some of) the amendments annexed to this report and listed below had not been made, since they have been considered to go beyond the disclosure as filed, as indicated in the Supplemental Box (Rule 70.2(c)).
 - the description, pages
 - the claims, Nos.
 - the drawings, sheets/figs
 - the sequence listing (*specify*):
 - any table(s) related to sequence listing (*specify*):

* If item 4 applies, some or all of these sheets may be marked "superseded."

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Box No. III Non-establishment of opinion with regard to novelty, inventive step and industrial applicability

1. The questions whether the claimed invention appears to be novel, to involve an inventive step (to be non-obvious), or to be industrially applicable have not been examined in respect of:
 - the entire international application,
 - claims Nos. 51,52(partially)
because:
 - the said international application, or the said claims Nos. relate to the following subject matter which does not require an international preliminary examination (specify):
 - the description, claims or drawings (*indicate particular elements below*) or said claims Nos. are so unclear that no meaningful opinion could be formed (*specify*):
 - the claims, or said claims Nos. are so inadequately supported by the description that no meaningful opinion could be formed.
 - no international search report has been established for the said claims Nos. 51,52(partially)
 - the nucleotide and/or amino acid sequence listing does not comply with the standard provided for in Annex C of the Administrative Instructions in that:

the written form	<input type="checkbox"/> has not been furnished
	<input type="checkbox"/> does not comply with the standard
the computer readable form	<input type="checkbox"/> has not been furnished
	<input type="checkbox"/> does not comply with the standard
 - the tables related to the nucleotide and/or amino acid sequence listing, if in computer readable form only, do not comply with the technical requirements provided for in Annex C-bis of the Administrative Instructions.
 - See separate sheet for further details

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Box No. IV Lack of unity of invention

1. In response to the invitation to restrict or pay additional fees, the applicant has:
 - restricted the claims.
 - paid additional fees.
 - paid additional fees under protest.
 - neither restricted nor paid additional fees.
2. This Authority found that the requirement of unity of invention is not complied with and chose, according to Rule 68.1, not to invite the applicant to restrict or pay additional fees.
3. This Authority considers that the requirement of unity of invention in accordance with Rules 13.1, 13.2 and 13.3 is
 - complied with.
 - not complied with for the following reasons:
see separate sheet
4. Consequently, this report has been established in respect of the following parts of the international application:
 - all parts.
 - the parts relating to claims Nos. .

Box No. V Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

1. Statement

Novelty (N)	Yes:	Claims	17,28,29,32-34,36-45,49-52
	No:	Claims	1-16,18-27,30,31,35,46-48
Inventive step (IS)	Yes:	Claims	17,28,29,32-34,36-45,49-52
	No:	Claims	1-16,18-27,30,31,35,46-48
Industrial applicability (IA)	Yes:	Claims	1-52
	No:	Claims	

2. Citations and explanations (Rule 70.7):

see separate sheet

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Supplemental Box relating to Sequence Listing

Continuation of Box I, item 2:

1. With regard to any **nucleotide and/or amino acid sequence** disclosed in the international application and necessary to the claimed invention, this report has been established on the basis of:
 - a. type of material:
 a sequence listing
 table(s) related to the sequence listing
 - b. format of material:
 in written format
 in computer readable form
 - c. time of filing/furnishing:
 contained in the international application as filed
 filed together with the international application in computer readable form
 furnished subsequently to this Authority for the purposes of search and/or examination
 received by this Authority as an amendment on
2. In addition, in the case that more than one version or copy of a sequence listing and/or table(s) relating thereto has been filed or furnished, the required statements that the information in the subsequent or additional copies is identical to that in the application as filed or does not go beyond the application as filed, as appropriate, were furnished.
3. Additional observations, if necessary:

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Re Item III.

- 1)The expressions "variants" and "fragments" comprises a wide range of compounds, embracing a great variety of possibilities not yet explored by the applicant, the effect of which cannot be foreseen having regard to the problem to be solved. Furthermore it cannot be expected from the skilled person using the teaching disclosed in the current application and his technical knowledge to be able to reproduce without undue burden all the possibilities which are actually claimed, thus violating Artt.5/6 PCT to such a extent that no complete search could have been performed. Hence the search and consequently the examination of said variants and fragments has been restricted to variants defined in claim 3 and the relevant fragments chosen from the fragments having sequences defined by the SEQ ID Nos 52-119.
- 2)The claims 52 and (to a certain extent) 51 relate to a diagnostic method whereby one or two (sensitized) cells with reduced or different level of a polypeptide according to the invention are used and their response to an antibacterial or an inhibiting compound is determined. However due to the broad definition it could well be that the antibacterial or inhibiting compound reacts with cell fragments different from said polypeptide. Said claims are therefore considered to be so unclear that the search and consequently the examination has been restricted to compounds which specifically interact with said polypeptide.

Re Item IV.

The separate inventions/groups of inventions are:

Inventions 1-4:

Composition comprising a surface-located Campylobacter polypeptide, an antigenic fragment of variant thereof, a polynucleotide encoding it, an expression vector comprising said DNA, a recombinant cell comprising said DNA or said vector, an antibody capable of binding said polypeptide, their preparation and their compositions for medical or diagnostic use, wherein the polypeptide is respectively chosen from SEQ ID No 1,25,36 and 43 and the fragments comprise a relevant fragment thereof as defined by SEQ ID Nos 52-119

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They are not so linked as to form a single general inventive concept (Rule 13.1 PCT) for the following reasons:

- 1)Reading the claims in the light of the description the problem to be solved could initially be considered to be the provision of *Campylobacter* antigens to be used in vaccines, in the preparation of antibodies and for diagnostic purposes.
- 2)This problem has been solved by a plurality of solutions as defined in claim 1 by SEQ ID Nos 1,25,36,43, being all surface-located polypeptides, and variants or fragments thereof. The application further relates to pharmaceutical compositions containing said compounds, antibodies thereto, recombinant cells encoding said polypeptides, their preparation and use.
- 3)The closest prior art consists of a multitude of documents all relating to surface-located *Campylobacter (jejuni)* antigens and their use in vaccines, etc., as can be exemplified by the following documents:
 - a)CA-A-2296869, disclosing a surface-located polypeptide JlpA from *Campylobacter jejuni* and its use in vaccines and for diagnostic purposes (e.g., see abstract and page 3, lines 7-8);
 - b)US-A-5470958, disclosing the surface antigens PEB1 and PEB3 from *Campylobacter jejuni* and vaccines comprising them (e.g., see abstract and column s 3-4);
- 4)In the light of these documents, the objective problem could therefore be considered to be the provision (and use) of alternative surface-located *Campylobacter* antigens.
- 5)Therefore in order to fulfil the requirements of Rule 13 PCT the polypeptides should share a common structural domain which may be regarded as the special technical feature providing unity; this special technical feature should be an essential structural part common to all of the embodiments of the claimed invention (and responsible for the inventive effect), and which should be absent from any solution to the same problem disclosed in the prior art.
- 6)Regarding all of the proposed solutions as a whole, as defined in claim 1, no common invariant domains of this type can be identified as being present in said polypeptides, which could be regarded as the special technical feature providing unity to the application.
- 7)As no other technical features can be distinguished which, in the light of the prior art, could be considered as special technical features on which a unifying concept could be based, there is lack of unity between the plurality of claimed inventions defined in, inter alia, claim 1 of the present application (see Rule 13.1 PCT).

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Re Item V.

Reference is made to the following documents:

D1: Database GSP, 16 June 2003, XP2334809, database accession no. ABU26391

D2: WO-A-02077183

D3: US-A-5470958

D4: CA-A-2296869

D5: DATABASE UniProt 15 October 2000 (2000-10-15), XP002326090

Database accession no. Q9PJ34

D6: DATABASE UniProt 1 October 2000 (2000-10-15), XP002334638

Database accession no. Q9PM33

D7: DATABASE UniProt 1 October 2000 (2000-10-15), XP002334639

Database accession no. Q9NS2

D8: DATABASE UniProt 1 October 2000 (2000-10-15), XP002334640

Database accession no. Q9PI85

D9: ALLAN E ET AL: "Genes to genetic immunization: identification of bacterial vaccine candidates" METHODS : A COMPANION TO METHODS IN ENZYMOLOGY, ACADEMIC PRESS INC., NEW YORK, NY, US, vol. 31, no. 3, November 2003 (2003-11), pages 193-198, XP004457831 ISSN: 1046-2023

Remark:

It is confirmed that D8 should refer to the database entry Q9PI85. Inadvertently a document based on the entry Q9P185 has been sent with the ISR.

I.Novelty

1)D1 and D2 disclose the polypeptide with sequence 54315 or fragments thereof, DNA encoding them, antibodies thereto and their medical and diagnostical use (see the relevant citation places in the ISR).

This polypeptide is identical to the present polypeptide having SEQ ID No.43, rendering

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the claims 1-16,18-27,30,31,35,46-48 not novel under Art.33(2) PCT.

The applicant has submitted that this invention is based on a selection from a large number of polypeptides and a large number of uses as mentioned in D2 and that D2 does not disclose the specific use as a vaccine of this specific polypeptide.

However claim 1 and the related claims are not restricted to this specific use but rather claim a first medical use, that is, "as a medicament", which cannot be considered to represent a selection from two lists.

2)In view of the available prior art the present claims 17,28,29,32-34,36-45,49-52 are considered to be novel.

II.Inventive step

A)Subject-matter relating to the polypeptides based on the SEQ ID Nos 1,25 and 36:

1)The closest prior art is considered to be documents D3 and D4, disclosing surface-located *Campylobacter jejuni* antigens which are, *inter alia* used for vaccination.
2)The present subject-matter essentially only differs in the structure of the surface-located antigen, being SEQ ID No.1,25 or 36 and their respective fragments with SEQ ID Nos. 52-62, 96-102 and 109-119 and also the fragments with SEQ ID Nos. 74-81, originating from SEQ ID No 43.

3)The problem to be solved may therefore be considered to be the provision of alternative surface-located *Campylobacter* antigens for use, *inter alia*, in vaccines, preparation of antibodies and diagnostic purposes.

4)The polypeptides with SEQ ID Nos. 1,25,36 and 43 were already disclosed in respectively D5-D8, which disclosures furthermore indicated that said proteins are putative periplasmic proteins, however were silent about a medical use thereof.

The remaining question in order to establish inventive step is therefore whether it could have been expected that the polypeptides with SEQ ID No. 1,25 and 36 and the relevant fragments would have antigenic properties and be oriented at the cell-surface, allowing them to be used in vaccines.

5)D9 discloses a scheme for identification of bacterial vaccine candidates. A major step in that scheme is to identify the localization of the putative vaccine candidate, e.g., whether it is available outside or on the surface of the bacteria. Periplasmic proteins are thereby considered to be surface-located and therefore suitable for expression and testing.

6)In this respect the applicant has submitted that for a protein to be useful to generating a

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protective immune response at least the following criteria must be fulfilled:

- a)the protein must in fact be produced (the gene must be expressed), at a sufficient level;
- b)the protein must be translocated across the cytoplasmic membrane, further transported to the cell-surface and actually be exposed to the extracellular space; in this respect the applicant has made plausible that a periplasmic protein not necessary is exposed on the cell-surface;
- c)it must be possible to produce a protein in a heterologous host, purify it and store it without loss of secondary structure;
- d)the protein must be immunogenic in a mammal and the immune response in the mammal must be protective.

In the opinion of the examiner there is therefore an expectation that periplasmic proteins are suitable vaccine candidates and hence the antigenic properties of SEQ ID Nos. 1,25 and 36 would already have been expected on the mere fact that they are periplasmic proteins.

7)Having regard to these submissions, making plausible that for a polypeptide that on the basis of its DNA sequence is predicted to be a signal peptide there is no reasonable expectation that all of these criteria will be fulfilled, inventive step can be acknowledged for the present subject-matter based on the SEQ ID Nos 1,25 and 36.

B)Subject-matter relating to the polypeptides based on the SEQ ID No 43:

1)The reasoning of the applicant is acknowledged as to the claims 17,36,40,42 and dependent claims, which can be considered to be based on non-obvious selections from D2.

Hence the novel claims 17,28,29,32-34,36-45 and 49-52 are considered to fulfil the requirements of Art.33(3) PCT.

1
09. 12. 2005

Claims

(59)

1. A composition comprising

- a polypeptide which comprises a sequence selected from the group consisting of surface-located *Campylobacter* polypeptides of SEQ ID NO:1, 25, 36 and 43, or comprises an antigenic fragment or variant of said sequence,
- a polynucleotide comprising a sequence encoding said polypeptide,
- an expression vector comprising a sequence encoding said polypeptide,
- a recombinant virus or recombinant cell comprising said polynucleotide or said expression vector, or
- an antibody capable of binding said polypeptide,
for use as a medicament.

15 2. The composition of claim 1, wherein the composition comprises

- a polypeptide which comprises a sequence selected from the group consisting of SEQ ID NO:1, 25, 36 and 43, or comprises an antigenic fragment or variant of said sequence,
- a polynucleotide comprising a sequence encoding said polypeptide,
- an expression vector comprising a sequence encoding said polypeptide, or
- a recombinant virus or recombinant cell comprising said polynucleotide or said expression vector.

25 3. The composition of any of the preceding claims, wherein the variant has at least 95%, such as at least 96%, e.g. at least 97%, such as at least 98%, e.g. at least 99% sequence identity to said sequence.

30 4. The composition of any of the preceding claims, wherein the antigenic fragment comprises less than 99%, such as less than 75%, e.g. less than 50%, such as less than 25%, e.g. less than 20%, such as less than 15%, or e.g. less than 10% of the full-length of said sequence.

5. The composition of any of the preceding claims, wherein the antigenic fragment comprises less than 70 consecutive amino acid residues, e.g. less than 50, such

as less than 40, e.g. less than 30, such as less than consecutive 20 residues of said sequence.

6. The composition of any of the preceding claims, wherein the antigenic fragment
5 comprises 6 or more, such as 7 or more, e.g. 8 or more, such as 9 or more, e.g.
10 or more consecutive amino acids of said sequence.
7. The composition of any of the preceding claims, wherein the antigenic fragment
10 comprises one or more residues of a fragment selected from the group
consisting of SEQ ID NO:52-62, 74-81, 96-102, and 109-119, e.g. two or more
consecutive, such as three or more consecutive, e.g. four or more consecutive,
such as 5 or more consecutive resides, e.g. 6 or more consecutive residues of a
fragment selected from the group consisting of SEQ ID NO:52-62, 74-81, 96-
102, and 109-119.
15
8. The composition of any of the preceding claims, wherein the polypeptide
comprises a tag, such as a histidine tag.
9. The composition of any of the preceding claims, wherein the recombinant cell is
20 an attenuated or reduced-virulence Escherichia coli cell or an attenuated or
reduced-virulence Salmonella cell.
10. The composition of any of the preceding claims, wherein the recombinant cell is
alive.
25
11. The composition of any of the preceding claims, wherein the recombinant cell is
dead.
12. The composition of any of claims 2-11, wherein the medicament is a vaccine.
30
13. The composition of claim 12, wherein the composition comprises an
immunogenic carrier, such as a carrier protein, wherein the immunogenic carrier
preferably is bound to said polypeptide.

14. The composition of any of claims 12-13, wherein the composition comprises an adjuvant.
- 5 15. The composition of claim 1, wherein the composition comprises an antibody capable of binding a polypeptide selected from the group consisting of SEQ ID NO: 1,25, 36 and 43.
- 10 16. The composition of claim 15, wherein the antibody furthermore is capable of binding an intact *Campylobacter jejuni* cell.
- 15 17. The composition of claim 1, wherein the composition comprises an antibody capable of binding a polypeptide selected from the group consisting of SEQ ID NO:43 and capable of binding an intact *Campylobacter jejuni* cell.
- 20 18. The composition of any of claims 15 to 17, wherein the antibody is polyclonal.
- 25 19. The composition of any of claims 15 to 17, wherein the antibody is monoclonal.
- 20 20. The composition of any of claims 15 to 19, wherein the antibody is a human antibody or humanised antibody.
- 25 21. The composition of any of claims 15 to 20, wherein the antibody is a binding fragment of an antibody.
- 30 22. The composition of any of claims 15 to 21, wherein the antibody has a dissociation constant or Kd less than 5×10^{-6} M, such as less than 10^{-6} M, e.g. less than 5×10^{-7} M, such as less than 10^{-7} M, e.g. less than 5×10^{-8} M, such as less than 10^{-8} M, e.g. less than 5×10^{-9} M, such as less than 10^{-9} M, e.g. less than 5×10^{-10} M, such as less than 10^{-10} M, e.g. less than 5×10^{-11} M, such as less than 10^{-11} M, e.g. less than 5×10^{-12} M, such as less than 10^{-12} M, e.g. less than 5×10^{-13} M, such as less than 10^{-13} M, e.g. less than 5×10^{-14} M, such as less than 10^{-14} M, e.g. less than 5×10^{-15} M, or less than 10^{-15} M.
- 35 23. The composition of any of the preceding claims, wherein the composition comprises a pharmaceutically-acceptable carrier.

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24. The composition of any of the preceding claims, wherein the composition is suitable for systemic administration.
- 5 25. The composition of any of the preceding claims, wherein the composition is suitable for intravenous, intramuscular, or subcutaneous administration.
- 10 26. The composition of any of the preceding claims, wherein the composition is suitable for oral administration.
- 15 27. The composition of any of the preceding claims, wherein the composition is suitable for intranasal administration.
- 22 28. An antibody capable of binding a polypeptide selected from the group consisting of SEQ ID NO: 1,25 and 36.
29. The antibody of claim 28, wherein the antibody furthermore is capable of binding an intact *Campylobacter jejuni* cell.
- 20 30. An antibody capable of binding the polypeptide of SEQ ID NO:43 and capable of binding an intact *Campylobacter jejuni* cell.
- 25 31. The antibody of any of claims 28 to 30, comprising the features of any of claims 18 to 22.
- 30 32. A recombinant cell transformed or transfected with a polynucleotide comprising a sequence encoding a polypeptide, said polypeptide comprising a sequence selected from the group consisting of SEQ ID NO: 1,25 and 36, or comprising an antigenic fragment or variant of said sequence.
- 35 33. The recombinant cell of claim 32, wherein the recombinant host cell is an *Escherichia coli* or *Salmonella* cell.
34. The recombinant cell of claim 32 or 33, wherein recombinant the cell is an attenuated or reduced-virulence cell.

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35. A recombinant attenuated or reduced-virulence Escherichia coli or recombinant attenuated or reduced-virulence Salmonella cell transformed or transfected with a polynucleotide comprising a sequence encoding the polypeptide of SEQ ID NO:43, or comprising an antigenic fragment or variant of said sequence.
- 5
36. Use of
- 10 - a polypeptide which comprises a sequence selected from the group consisting of SEQ ID NO: 1,25, 36 and 43, or comprises an antigenic fragment or variant of said sequence,
- 15 - a polynucleotide comprising a sequence encoding said polypeptide,
- an expression vector comprising a sequence encoding said polypeptide, or
- a recombinant virus or recombinant cell comprising said polynucleotide or said expression vector,
- 15 for the preparation of a medicament for the immunisation of an animal or human being against Campylobacter, preferably Campylobacter jejuni, infections.
37. The use of claim 36, wherein the immunisation induces a protective immune response.
- 20
38. The use of claim 36 or 37, wherein the medicament is a medicament suitable for parenteral, intravenous, intramuscular, subcutaneous, oral or intranasal administration.
- 25
39. The use of any of claims 36-38, wherein the medicament further comprises an adjuvant.
- 30
40. Use of an antibody capable of binding a polypeptide selected from the group consisting of SEQ ID NO:1,25, 36 and 43, preferably an antibody as defined in any of claims 28 to 31, for the manufacture of a medicament for the treatment or prevention of Campylobacter, preferably Campylobacter jejuni, infections in an animal or human being.

41. A method for raising antibodies to a polypeptide selected from the group consisting of SEQ ID NO:1,25 and 36 in a non-human animal comprising the steps of

a. providing

- 5 - a polypeptide comprising a sequence selected from the group consisting of SEQ ID NO:1,25 and 36, or comprising an antigenic fragment or variant of said sequence,
 - a polynucleotide comprising a sequence encoding said polypeptide,
 - an expression vector comprising a sequence encoding said polypeptide,
10 or
 - a recombinant virus or recombinant cell comprising said polynucleotide or said expression vector,
- 15 b. introducing a composition comprising said polypeptide, polynucleotide, vector, recombinant virus or recombinant cell into said animal,
- c. raising antibodies in said animal, and
- d. isolating and optionally purifying the antibodies.

42. A method for raising antibodies to the polypeptide of SEQ ID NO:43 in an non-human animal, wherein the antibodies are capable of binding an intact *Campylobacter jejuni* cell, the method comprising the steps of

a. providing

- 20 - a polypeptide comprising the sequence of SEQ ID NO:43, or comprising antigenic fragment or variant of said sequence,
 - a polynucleotide comprising a sequence encoding said polypeptide,
 - an expression vector comprising a sequence encoding said polypeptide,
25 or
 - a recombinant virus or recombinant cell comprising said polynucleotide or said expression vector,
- 30 b. introducing a composition comprising said polypeptide, polynucleotide, vector, recombinant virus or recombinant cell into said animal,
- c. raising antibodies in said animal,
- d. isolating and optionally purifying the antibodies, and
- e. selecting antibodies capable of binding an intact *Campylobacter jejuni* cell.

43. The method of claim 41 or 42, wherein the animal is a transgenic animal capable of producing human antibodies.
44. A method for detecting *Campylobacter jejuni* or parts thereof in a sample comprising the steps of
5 a. contacting said sample with an indicator moiety capable of specifically binding a polypeptide selected from the group consisting of SEQ ID NO: 1,25, and 36, and
10 b. determining whether a signal has been generated by the indicator moiety, thereby detecting whether said sample contains *Campylobacter jejuni* or parts thereof.
45. The method of claim 44, wherein the indicator moiety furthermore is capable of binding intact *Campylobacter jejuni* cells.
- 15 46. A method for detecting *Campylobacter jejuni* in a sample comprising the steps of
20 a. contacting said sample with an indicator moiety capable of specifically binding the polypeptide of SEQ ID NO:43, wherein the indicator moiety furthermore is capable of specifically binding intact *Campylobacter jejuni* cells, and
25 b. determining whether a signal has been generated by the indicator moiety, thereby detecting whether said sample contains *Campylobacter jejuni*.
47. The method of any of claims 44 to 46, wherein said indicator moiety does not pass through the outer membrane of a *Campylobacter jejuni* cell.
- 25 48. The method of any of claims 44 to 47, wherein said indicator moiety consist of or comprises an antibody, such as an antibody as defined in any of claims 28 to 31.
- 30 49. A method for identifying a binding partner of a polypeptide selected from the group consisting of SEQ ID NO:1,25 and 36 or a fragment thereof, comprising the steps of
35 a. providing a polypeptide selected from the group consisting of SEQ ID NO:1,25 and 36 or a fragment thereof,
 b. contacting said polypeptide or fragment with a putative binding partner, and

- c. determining whether said putative binding partner is capable of binding to said polypeptide or fragment.
- 5 50. A method for identifying a compound with antibacterial activity against *Campylobacter jejuni* comprising the steps of
- a. providing a sensitised cell which has a reduced level of a polypeptide selected from the group consisting of SEQ ID NO:1,25 and 36, and
 - b. determining the sensitivity of said cell to a putative antibacterial compound, for instance by a growth assay.
- 10 51. A method for identifying an inhibitor of a polypeptide selected from the group consisting of SEQ ID NO:1,25 and 36, comprising the steps of
- a. providing two cells which differ in the level of a polypeptide selected from the group consisting of SEQ ID NO:1,25 and 36,
 - b. determining the sensitivity of said cells to a putative inhibitor, for instance by a growth assay, and
 - c. determining whether said two cells are differently affected by the presence of said putative inhibitor.
- 15 52. The method of claim 51, wherein the putative inhibitor does not pass through the outer membrane of a *Campylobacter jejuni* cell.
- 20